

Attorney Docket No.: **DEX-0142**
Inventors: **Macina et al.**
Serial No.: **09/802,674**
Filing Date: **March 9, 2001**
Page 2

REMARKS

Claim 1 is pending in the instant application.

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement.

The Examiner has acknowledged the specification to be enabling for a method for detecting the presence of gastrointestinal cancer in a patient comprising determining levels of SEQ ID NO:3 in cells, tissue or bodily fluids in a patient and comparing the determined levels of SEQ ID NO:3 in cells, tissue or bodily fluids from a normal human control, wherein at least a two-fold decrease in determined levels of SEQ ID NO:3 in said patient versus normal human control is associated with presence of gastrointestinal cancer. However, the Examiner suggests that the specification does not reasonably provide enablement for a method for detecting the presence of gastrointestinal cancer in a patient comprising determining levels of a polynucleotide encoding a polypeptide comprising SEQ ID NO:4.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that the Examiner's suggestion in the instant Office Action that the specification does not reasonably provide enablement for a method

Attorney Docket No.: **DEX-0142**
Inventors: **Macina et al.**
Serial No.: **09/802,674**
Filing Date: **March 9, 2001**
Page 3

for detecting the presence of gastrointestinal cancer in a patient comprising determining levels of a polynucleotide encoding a polypeptide comprising SEQ ID NO:4 directly contradicts the Examiner's statements in the Office Action of October 14, 2003 and April 7, 2003 wherein this subject matter was acknowledged to be enabled. See paragraph 4 bridging pages 2-3 of the October 4, 2003 Office Action or paragraph 7 at page 7 of the April 7, 2003 Office Action wherein that Examiner states that:

the specification while being enabling for a method for diagnosing the presence of gastrointestinal cancer in a patient comprising determining levels of a polynucleotide comprising SEQ ID NO:3 or a polynucleotide encoding a polypeptide comprising SEQ ID NO:4 in cells tissue or bodily fluids . . . , does not reasonably provide enablement for methods of diagnosing metastases, staging and monitoring changes in gastrointestinal cancer.

Applicants relied upon the Examiner's statement and the acknowledgment of enabled subject matter when amending the claims and formulating arguments for the last two responses. To change the identification of enabled subject matter at this point in the prosecution, based solely upon the Examiner's suggestion that there is a lack of support in the specification for enablement of this claim and not any other showing of a reasonable basis to question the enablement clearly does not meet the required burden

Attorney Docket No.: **DEX-0142**
Inventors: **Macina et al.**
Serial No.: **09/802,674**
Filing Date: **March 9, 2001**
Page 4

for this rejection as set forth in MPEP § 2164.03.

Further, Applicants are submitting herewith a Supplemental IDS inclusive of reference BE by Kivelä et al. (Digestive Diseases and Sciences, Vol. 46, No. 10 October 2001) which provides evidence establishing that carbonic anhydrase, the polypeptide of SEQ ID NO:4 is decreased in colon cancer. Thus, as shown by this reference, polypeptide expression mimics the polynucleotide expression levels taught in the instant specification. It is well known in the art that, due to degeneracy of the genetic code, the polypeptide disclosed by Kivelä et al. may be encoded by various polynucleotides. Absent any showing whatsoever by the Examiner otherwise, the evidence set forth in Kivelä et al. (that this protein is downregulated in the same fashion as the polynucleotide of SEQ ID NO:3 as taught in the instant specification), provides a reasonable expectation that other polynucleotides encoding SEQ ID NO:4 will exhibit the same expression patterns.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph for lack of enablement is therefore respectfully requested.

Claim 1 has also been rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in

Attorney Docket No.: **DEX-0142**
Inventors: **Macina et al.**
Serial No.: **09/802,674**
Filing Date: **March 9, 2001**
Page 5

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claim invention. The Examiner has acknowledged SEQ ID NO:3 and the encoded polypeptide SEQ ID NO:4 to be taught. However, the Examiner suggests that the skilled artisan cannot envision all the nucleic acids and the detailed structure of the encompassed polypeptides that are applicable to the claimed method drawn to polynucleotides encoding SEQ ID NO:4.

Applicants respectfully traverse this rejection.

MPEP § 2163 at page 2100-169 states that:

if an applicant discloses an amino acid sequence it is not necessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that applicant was in possession of the full genus of nucleic acids encoding a given sequence . . .

Applicants have provided in the instant application the amino acid sequence for SEQ ID NO:4 as well as a preferred polynucleotide species, SEQ ID NO:3. Thus, in accordance with MPEP §2163 and the holding of the Courts in *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529,1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994), Applicants were in possession of the full genus of

Attorney Docket No.: **DEX-0142**
Inventors: **Macina et al.**
Serial No.: **09/802,674**
Filing Date: **March 9, 2001**
Page 6

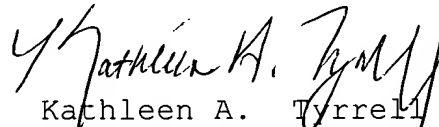
polynucleotides encoding SEQ ID NO:4, as claimed.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, for lack of written description is therefore respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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